

## Environmental Protection Agency

## § 766.16

EPA upon request by EPA or its authorized representative. Laboratories conducting testing for submission to EPA in response to a test rule promulgated under section 4 of TSCA must adhere to the TSCA Good Laboratory Practices (GLPs) published in part 792 of this chapter. Sponsors must notify the laboratory that the testing is being conducted pursuant to TSCA section 4. Sponsors are also responsible for ensuring that laboratories conducting the testing abide by the TSCA GLP standards. At the time test data are submitted, manufacturers must submit a certification to EPA that the laboratory performing the testing adhered to the TSCA GLPs.

### § 766.12 Testing guidelines.

Analytical test methods must be developed using methods equivalent to those described or reviewed in *Guidelines for the Determination of Polyhalogenated Dibenzo-p-dioxins and Dibenzofurans in Commercial Products*. Copies are available from the Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency, Room E-543B, 1200 Pennsylvania Ave., NW., Washington, DC 20460, Telephone: (202) 554-1404, TDD: (202) 544-0551. Publicly available docket materials are available at the addresses in § 700.17(b)(1) and (2) of this chapter.

[60 FR 34466, July 3, 1995, as amended at 77 FR 46292, Aug. 3, 2012]

### § 766.14 Contents of protocols.

Protocols should include all parts of the *Quality Assurance Plan for Measurement of Brominated or Chlorinated Dibenzofurans and Dibenzodioxins*, as stated in the Guidelines. For each chemical substance and each process, the manufacturer must submit a statement of how many grades of the chemical substance it produces, a justification for selection of the specific grade of chemical substance for testing, specific plans for collection of samples from the process stream, naming the point of collection, the method of collecting the sample, and an estimate of how well the samples will represent the material to be characterized; a description of how control samples (blanks)

and HDD/HDF-reinforced control samples, or isotopically labeled compounds (standards) and duplicate samples will be handled; a description of the chemical extraction and clean up procedures to be used; how extraction efficiency and measurement efficiency will be established; and a description of instrument hardware and operating conditions, including type and source of columns, carrier gas and flow rate, operating temperature range, and ion source temperature.

### § 766.16 Developing the analytical test method.

Because of the matrix differences of the chemicals listed for testing, no one method for sample selection, preparation, extraction and clean up is prescribed. For analysis, High Resolution Gas Chromatography (HRGC) with High Resolution Mass Spectrometry (HRMS) is the method of choice, but other methods may be used if they can be demonstrated to reach the target LOQs as well as HRGC/HRMS.

(a) *Sample selection.* The chemical product to be tested should be sampled so that the specimens collected for analysis are representative of the whole. Additional guidance for sample selection is provided under § 766.12.

(b) *Sample preparation.* The sample must be mechanically homogenized and subsampled as necessary. Subsamples must be spiked or reinforced with surrogate compounds or with standard stock solutions, and the surrogates or standards must be thoroughly incorporated by mechanical agitation. Additional guidance is provided under § 766.12.

(c) *Sample extraction and cleanup.* The spiked samples must be treated to separate the HDDs/HDFs from the sample matrix. Methods are reviewed in the Guidelines under § 766.12, but the final method or methods are left to the discretion of the analyst, provided the instrumental response of the surrogates meets the criteria listed in the *Quality Assurance Plan for Measurement of Brominated or Chlorinated Dibenzofurans and Dibenzodioxins*, Appendixes B and C of the Guidelines. Cleanup techniques are described in the Guidelines. These

are chosen at the discretion of the analyst to meet the requirements of the chemical matrix.

(d) *Analysis.* The method of choice is High Resolution Gas Chromatographic/High Resolution Mass Spectrometric Determination, (HRGC/HRMS) but alternate methods may be used if the manufacturer can demonstrate that the method will reach the target LOQs as well as HRGC/HRMS. Specific operating requirements are found in the Guidelines.

**§ 766.18 Method sensitivity.**

The target level of quantitation required under § 766.27 for each HDD/HDF congener is the level which must be attempted for each resolved HRGC peak for that congener. For at least one product sample, at least two analyses of the same isotopically labeled HDD/HDF internal calibration standards spiked to a final product concentration equal to the LOQ for that congener must be reproducibly extracted, cleaned up, and quantified to within  $\pm 20$  percent of each other. For each spiked product sample, the signal to noise ratio for the calibration standard peaks after complete extraction and cleanup must be 10:1 or greater. The recovery of the internal calibration standards in the extracted and cleaned up product samples must be within 50 to 150 percent of the amount spiked, and the results must be corrected for recovery.

**Subpart B—Specific Chemical Testing/Reporting Requirements**

**§ 766.20 Who must test.**

(a) Any person who manufactures, imports, or processes a chemical substance listed in § 766.25 must test that chemical substance and must submit appropriate information to EPA according to the schedules described in § 766.35. Chemical substances manufactured, imported or processed between January 1, 1984 and the date of promulgation of this part are subject to testing upon the effective date of this part. All other chemical substances are subject to testing immediately upon manufacture, import or processing. EPA expects that only manufacturers and importers will perform testing, and

that the cost of testing will be passed on to processors through the pricing mechanism, thereby enabling them to share in the cost of testing. However, processors will be called upon to sponsor testing should manufacturers and importers fail to do so. A processor may apply for an exemption from testing upon certification to EPA that a manufacturer or importer is testing the chemical substance which that person processes.

(b) If no manufacturer or importer described in § 766.20 submits a letter of intent to perform testing within the period described under § 766.35(a), or an exemption application under § 790.45(a), or a request for an exclusion or waiver under § 766.32, EPA will issue a notice in the FEDERAL REGISTER to notify all processors of that chemical substance. The notice will state that EPA has not received any of the documents described in the previous sentence, and that current processors will have 30 days to submit either a letter of intent to perform the test or submit an exemption application.

(c) If no manufacturer, importer or processor submits a letter of intent to perform testing of a specific chemical substance produced by a specific process, EPA will notify all manufacturers, importers, and processors, either by notice in the FEDERAL REGISTER or by letter, that all exemption applications will be denied and that within 30 days all manufacturers, importers, and processors will be in violation of this part until a proposed study plan is submitted for required testing.

(d) Manufacturers, importers, and processors who are subject to this part must comply with the test rule development and exemption procedures in part 790 of this chapter, except as modified in this part.

**§ 766.25 Chemical substances for testing.**

(a) *Listing of chemical substances.* Chemical substances required to be tested for HDDs/HDFs under this rule are listed in this section. The listing is by Chemical Abstracts Service (CAS) Number and common name.

NOTE: For purposes of guidance only, EPA lists the chemical substances subject to testing under this part in two classes—those